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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,951	02/04/2002	Keith Biggadeke	PG4734	6056

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EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/066,951

Applicant(s)

Biggadike

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 09/958,050.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_

**First Office Action on the Merits**

***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- u) 2. Claims 1, 2 and 4-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13 and 15-27 of copending Application No. 09/958,050. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a formulation comprising 17 $\alpha$ -(2-furanylcarbanoyloxy) ester of fluticasone and a container containing said formulation as well as a method of treating inflammatory and/or allergic conditions utilizing said formulation. The difference between the two applications is based on the scope of the claimed compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1616

3. Claims 1, 2 and 4-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/066,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a formulation comprising 17 $\alpha$ -(2-furanylcarbanoyloxy) ester of fluticasone and a container containing said formulation as well as a method of treating inflammatory and/or allergic conditions utilizing said formulation. The difference between the two applications is based on the scope of the claimed compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1, 2 and 4-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/066,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a formulation comprising 17 $\alpha$ -(2-furanylcarbanoyloxy) ester of fluticasone and a container containing said formulation as well as a method of treating inflammatory and/or allergic conditions utilizing said formulation. The difference between the two applications is based on the scope of the claimed compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1616

- u 5. Claims 1, 2 and 4-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/067,020. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a formulation comprising 17 $\alpha$ -(2-furanylcabanoyloxy) ester of fluticasone and a container containing said formulation as well as a method of treating inflammatory and/or allergic conditions utilizing said formulation. The difference between the two applications is based on the scope of the claimed compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims ~~1-3, 5~~, 9, 11 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sjoquist (WO 99/32089).

Sjoquist teaches a stable formulations of glucocorticosteroid/glucocorticosteroid ester comprising a surfactant for use in treating allergic and/or inflammatory diseases (see the entire article; especially page 2, lines 18-21; page 3, lines 3-11, lines 16-27;

Art Unit: 1616

page 5, lines 7-10, line 17 – page 6, line 5; page 8, lines 1-28; page 9, lines 4-18). The reference teaches (a) glucocorticosteroid ester such as fluticasone propionate (see page 6, line 23; page 11, claim 7); (b) surfactants such as poloxamer and polyoxyethylene sorbitan fatty acid esters (see page 5, line 24 – page 6, line 5); (c) the addition of one or more acceptable additives such as a modifying agent, for example glucose (see page 7, lines 18-29; 12, claim 11) and (c) administration by oral or nasal inhalation in pressurized metered dose inhalers (see page 1, lines 20-29; page 9, lines 5-8). The composition and method of use taught by the reference are encompassed by the instant claims.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 6-8, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sjoquist (WO 99/32089) in view of Adjei et al. ('294) and/or Straub et al. ('300).

Sjoquist teaches a stable formulations of glucocorticosteroid/glucocorticosteroid ester comprising a surfactant for use in treating allergic and/or inflammatory diseases (see the entire article; especially page 2, lines 18-21; page 3, lines 3-11, lines 16-27;

Art Unit: 1616

page 5, lines 7-10, line 17 – page 6, line 5; page 8, lines 1-28; page 9, lines 4-18). The reference teaches (a) glucocorticosteroid ester such as fluticasone propionate (see page 6, line 23; page 11, claim 7); (b) surfactants such as poloxamer and polyoxyethylene sorbitan fatty acid esters (see page 5, line 24 – page 6, line 5); (c) the addition of one or more acceptable additives such as a modifying agent, for example glucose (see page 7, lines 18-29; 12, claim 11) and (c) administration by oral or nasal inhalation in pressurized metered dose inhalers (see page 1, lines 20-29; page 9, lines 5-8).

Claim 4 differs from the reference by reciting the  $17\alpha$ -(2-furanylcarmoyloxy) ester of fluticasone.

Claim 6-8, 10 and 12 differ from the reference by reciting specific surfactants not exemplified by the reference.

However, (a) Adjei et al. teach aerosol formulations comprising medicaments such as fluticasone esters, such as furoate and the addition of cosolvents or surfactants (see col. 1, lines 7-10; col. 2, lines 26-27; col. 5, claim 3; col. 8, claims 24-26) and (b) Straub et al. teach formulations comprising drugs, such as fluticasone propionate, having low solubility and methods of making said formulations in order to enhance their rate of dissolution (see the entire article, especially col. 1, lines 11-14; col. 6, lines 41-42). Straub also teaches addition of other excipients such as hydrophilic polymers, sugars, surfactants (for example, Triton and polyoxyethylene sorbitan fatty acid esters) etc. (see col. 8, line 10 – col. 10, line 29). Therefore, the preparation of formulations taught by Sjoquist utilizing (a) any fluticasone ester, including those taught by Adjei and

(b) any surfactant, including Triton (octylphenoxypolyethoxyethanol) as taught by Straub, will the reasonable expectation of obtaining a stable formulation useful in treating allergic and/or inflammatory diseases would have been obvious to the skilled artisan in the art at the time of the invention. The motivation would be based on the desire to obtain additional formulations as taught the prior art having anti-allergic and anti-inflammatory properties.

#### ***Other Matters***

10. Claim 3 recites the phrase "(i.e. the fluticasone ester is fluticasone propionate)" in line 2. It is suggested that said phrase be deleted because it does not add to the clarity of the instant claim.

#### ***Telephone Inquiry***

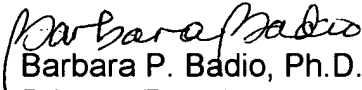
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.



Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
January 23, 2003